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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 829,631	04 10 2001	David R. Sibley	NIH047 1CP1C1	7640

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 02 20 2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/829,631

Applicant(s)

SIBLEY ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 17-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 17-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments filed 12/13/02 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant requests that original claims 1-37 be cancelled and that these claims were incorporated by reference to a parent application in the transmittal sheet. Applicant is under a misapprehension that incorporation of a document by reference results in these claims as being pending and/or under consideration. Parent claims 1-37 have never been pending claims in the present application and as such cannot be cancelled. Furthermore, it is noted that PCT/US93/10296 as originally filed had 38 not 37 claims. Note that the text (including claims) of the originally filed document is what is incorporated by reference and would not include any Article 34 amendments. Thus, it is the claims of the published PCT that are incorporated by reference. Originally filed claims 1-16 have not been renumbered as requested although they have been cancelled as requested. Newly presented claims 54-65 have been added as requested but renumbered as 17-28 under 37 CFR 1.126. The dependencies of these claims have also been corrected.

Applicant is advised that in view of originally filed claims 1-16, this application remains a continuation-in-part application and a new oath is required as set forth in the prior Office action. This status will not change even if the presently pending or any future claims have basis

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in the parent applications and are granted benefit of that priority date. Once again, as filed, this application constituted a continuation-in-part application.

Claim Rejections - 35 USC § 112

Claims 17-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The priority statement in the first paragraph of the specification indicates that the instant application is a continuation of 08/428,242 which is the national stage filing under 35 USC 371 of PCT/US93/10296 which is a continuation in part of 07/970,338. The transmittal sheet filed in the instant application indicates that the entire disclosure of the prior application is incorporated by reference. First of all, as set forth above, the instant application is a continuation in part of application 08/428,242. Secondly, the incorporation by reference in the transmittal sheet refers to only the 08/428,242 application and no other application. Further review of the 08/428,242 application reveals that the specification, including the claims, originally filed was **not** a copy of the international application as filed or published. (See transmittal sheet in 08/428,242.) Note that the specification filed in the 08/428,242 application improperly included the Article 34 amendments which substantively changed the claims. (Compare claims from WO 94/10310 that is the published form of PCT/US93/10296 to those claims originally filed in 08/428,242.) The 08/428,242 application should have contained the same claims as those in WO 94/10310. For the purposes of discussing the new matter rejection, basis for the presently filed claims will be

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considered with respect to basis in WO 94/10310. All page references will be with respect to this document.

The preamble of newly presented claim 17 recites, "exhibiting high affinity binding for clozapine, loxapine and amoxipine as determined by having a K_i value under 100 nM" with respect to (a) through (d). Part (c) is directed to nucleotide sequences that hybridize under particular conditions.

Page 19, first paragraph, discloses high affinity binding (having a K_i under 100 nM) with respect to clozapine, loxapine, amoxipine, clomiprimine, and amitriptyline for only the rat St-B17 serotonin receptor. Note that this section does not disclose binding with respect to the subset clozapine, loxapine, and amoxipine. It does not disclose this binding with respect to the human St-B17 serotonin receptor of parts (b) and (d) or an St-B17 serotonin receptor for any other species (i.e. mouse, bovine) encompassed by part (c).

Example 9 at page 22 discloses using the rat St-B17 serotonin receptor sequence fragments and conditions named in part (c) to clone the human sequence from a particular human genomic library (Stratagene # 946205). There is no contemplation of generic St-B17 sequences encoding receptors having the properties recited in the preamble.

Applicant is advised that they would have support for claims directed to nucleotide sequences SEQ ID NOS: 7 and 12 and amino acid sequences SEQ ID NOS: 8 and 13 in the absence of limitations to functional properties.

Claim Rejections - 35 USC § 102

Claims 17-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Sibley et al. (WO 94/10310).

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As presently written, no claim has complete support in the parent applications relied upon for priority for the reasons as set forth above. As such, applicant is entitled to benefit of the instant filing date of 4/10/01 and Sibley et al. (WO 94/10310) is valid prior art under 35 U.S.C. 102(b).

Sibley et al. discloses cloning and expression of the rat and human St-B17 serotonin receptor. Vectors and host cells are disclosed. The sequences disclosed would meet the limitations of part (c) of claim 17. See abstract, claims, and figures.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 8:30 am - 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for

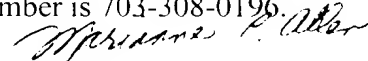
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the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Marianne P. Allen

Primary Examiner

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mpa

February 14, 2003